



Temporal Trends in Insertion of Implantable Cardioverter Defibrillators from an Australian Regional Tertiary Centre's Perspective

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Abstract

Background: Implantable Cardioverter Defibrillator (ICD) therapy is now standard therapy for prevention of Sudden Cardiac Death (SCD) in high-risk patients. In 2006, the Medical Services Advisory Committee (MSAC) reviewed the role of ICDs and approved them to be used for both primary and secondary prevention. This study reviews the temporal trends in indications for insertion of ICD at Geelong Cardiology Practice (GCP).

Methods: We retrospectively audited the files of GCP patients receiving their first ICD between 1990 and 2013.

Results: 393 patients received their device within the study period. The mean age at insertion was 66. The majority of the devices inserted were stand-alone ICDs 79% (n = 311) of which 138 were for primary prevention and 173 for secondary prevention. After their approval in 2006 there was significant increase in number of devices inserted for primary prevention, however the annual numbers for secondary prevention did not show any major changes ($p = 0.0001$). In 2006, the ICD and CRT first implant rate was 46 per 100,000 inhabitants, while in 2011 the first implant rate increased to 120 per 100,000 inhabitants. The majority of devices for primary prevention were for Ischaemic Cardiomyopathy (24.4%) and the most common arrhythmia for secondary prevention was Ventricular Tachycardia (28.5%) of which 71.4% was of ischaemic origin and 28.5% was of non-ischaemic origin. All-cause mortality over the study period was low at 7.88% (n = 31).

Conclusion: After approval for primary prevention in 2006, there was a dramatic increase in the number of ICDs inserted for this indication. Ischaemic Cardiomyopathy was the most common indication for primary prevention and Ventricular Tachycardia associated with ischaemic LV dysfunction was the most common arrhythmia in the secondary prevention group.

Keywords

Cardiomyopathy, Sudden cardiac death, Implantable cardioverter defibrillator, Heart failure

Background

Despite advances in emergency care and major advances in resuscitation methods, sudden cardiac death remains a major burden on public health. Majority of patients who have an Out of Hospital

Cardiac Arrest do not survive [1,2]. Those who are successfully resuscitated may have residual cognitive and motor deficits, which are variable depending on the time required to achieve a stable cardiac rhythm. In the 1970s, motivated by the death of a colleague, Drs Michel Mirowski and Morton Mower and colleagues conceptualised the first idea of an implantable device that can monitor the cardiac rhythm and deliver a shock if ventricular arrhythmia was detected [3,4]. In 1980 the first defibrillator was inserted in a young woman after a recent ventricular fibrillation arrest [5]. Subsequently the designs of the ICDs have improved and a series of observational studies demonstrated that the ICD appeared to be clinically useful. Following these observational studies, large randomised controlled trials showed that in patients with previous or symptomatic ventricular arrhythmias, mortality was significantly reduced by the ICDs as compared to optimal medical therapy [6,7].

A second series of trials were conducted and they showed that the ICDs also reduced mortality in patients with impaired left ventricular function due to previous myocardial infarction or heart failure [8]. There is now a widespread agreement that ICD is standard of care for reducing the mortality in a wide range of patients with increased risk factors for sudden cardiac death. This has led to development of standardised guidelines for insertion of ICD [9,10].

On review of the strength of the evidence for safety and cost effectiveness of the devices for prevention of Sudden Cardiac Death, in 2006, the Medical Services Advisory Committee of the Australian Government published its recommendations for the use of ICD in prevention of primary as well as secondary prevention [11].

While the clinical indications for the use of ICDs are now widely accepted, it is not clear that the clinical practice is consistent with the current guidelines [12-14]. Therefore in order to realise the true potential of reduction in sudden cardiac death that is offered by ICDs it is pertinent to audit current practice and outcomes in patients receiving ICDs and to identify barriers to ICDs. This study was conducted to address the first of these goals by reviewing the temporal trends in insertion of ICDs at Geelong Cardiology Practice, part of The University Hospital Geelong one of the large Victorian regional Tertiary centres. This study reviewed the devices inserted between 1990 and 2013.

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Table 1: Patient demographics and treatment details.

		Total (n = 393)		P value
		Before MSAC	After MSAC	
Gender	Male	72	231	0.601
	Female	19	71	
Indication	Primary	21	191	0.0001
	Secondary	70	111	
Types of Devices	Defib	90	221	0.0001
	BiV/Defib	1	62	
	BiV	0	19	

Methods

This was a retrospective observational study. We reviewed all the patient files receiving their first ICD at The University Hospital Geelong from the period of 1st January 1990 to 31st December 2013, and included clinical data from this time period. Population data was obtained from the Australian Bureau of Statistics 2006 and 2011 census of Population and Housing for the Geelong region. This study was reviewed by the Barwon Health Research Office and was advised that this project is exempt from ethical review as outlined in the National Statement on Ethical conduct in Human Research Section 5.

We collected data on the indications for ICD implantation, details of the type of device and the patient demographics and mortality. This was done by reviewing the implant records, cardiologist's letters and hospital records for each patient. The ICD indications were classified into primary and secondary prevention.

The primary prevention included patients with Ischaemic cardiomyopathy, Dilated cardiomyopathy, Hypertrophic Cardiomyopathy and Miscellaneous category which has been classified as "Other" which include Cardiomyopathy secondary to Wolff-Parkinson-White, complete heart block, hemochromatosis, Denon's Cardiomyopathy, Long QT syndrome and idiopathic cardiomyopathy.

The secondary prevention group were the ones who had a previous ventricular tachycardia (VT) or ventricular fibrillation (VF) cardiac arrest, syncopal VT or sustained VT. Non-sustained non-syncopal VT was classified as primary prevention, as well as all other indications in which VT/VF had not occurred prior to implantation.

To quantify the trends of devices used after MSAC approval, primary outcome was defined as trend of rate of devices used before and after MSAC approval. Secondary outcomes were defined as trend of rates of primary/secondary prevention and types of devices used.

a) Inclusion Criteria: All the patients who had their first device inserted at the University Hospital Geelong between 1st January 1990 and 31st December 2013 were included in this study.

b) Exclusion Criteria: Any Presentation for battery or a generator replacement was excluded from the study.

Data Analysis - Discrete variables were compared using the Pearson Chi Square test. All statistical tests were performed using the SPSS software v22.0.0.0 IBM Corporation.

Results

Over the twenty-three years of the study period, 393 patients received their first device. The mean age of insertion was 66yrs (SD of 12.6; Range 19-90) and patients were predominantly male (n = 303, 77%). The demographic details of all the patients are given in Table 1. Figure 1 shows the age groups across all the indications.

In 2006, the ICD and CRT first implant rate was 46 per 100,000 inhabitants, while in 2011 the first implant rate increased to 120 per 100,000 inhabitants [15].

In 2006 the first implant rate per 100,000 inhabitants for ICD was 45, BiV/Defib was 0.5 and BiV was 0, respectively. In 2011 the rates increased to 88 for ICD, 24 for BiV/Defib and 7 for BiV [15].

The majority of devices inserted were stand alone ICDs (79%, n

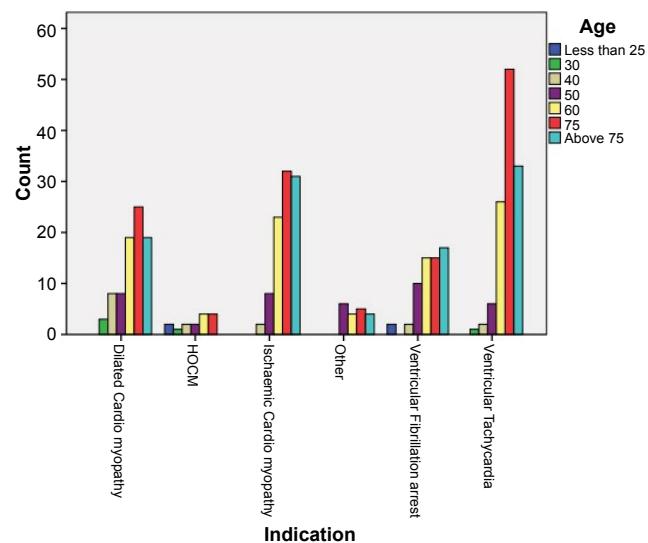


Figure 1: Age groups across all indications.

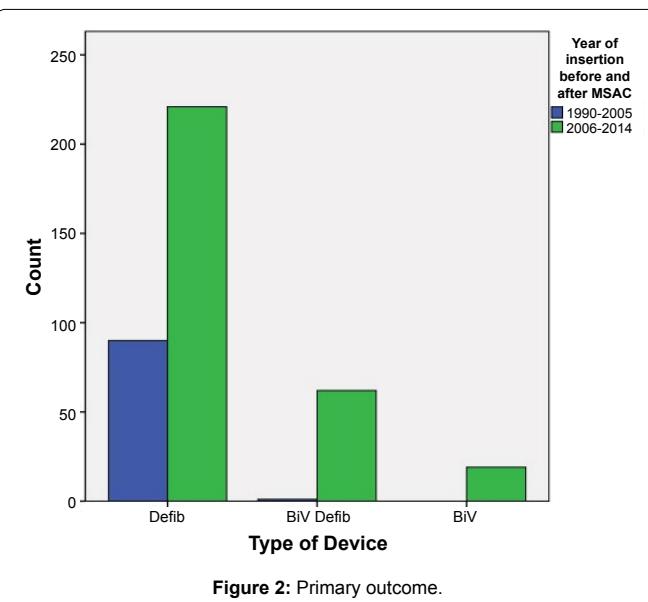


Figure 2: Primary outcome.

= 311) of which 138 were for primary prevention and 173 were for secondary prevention. The remainder of the devices were cardiac resynchronisation devices (CRT) - Bi-ventricular pacing with the defibrillator (BiV/Defib) i.e. CRT-D or Bi-ventricular pacing (BiV) only i.e. CRT-P. The BiV devices were first implanted in 2003. While the percentage of these devices being implanted increased after their approval by MSAC, they still accounted for less than 5% of the new devices being implanted. Over the study period, the majority of devices inserted were for primary prevention (n = 212). As depicted in the Table 1 there was no statistical difference between males and females getting a device before and after MSAC approval (p = 0.601). There was a significant statistical difference between the devices inserted for primary vs. secondary prevention before and after MSAC approval (p = 0.0001). Figure 2 shows the trends in rates of devices used before and after MSAC approval, which is the primary outcome of the study. It was also noted that there was a significant difference in the types of devices used before and after MSAC with ICDs being the most commonly used device (p = 0.0001). Figure 3 and Figure 4 depict secondary outcomes. Figure 3 illustrates the trends in the types of devices implanted over the study period and Figure 4 depicts the trends in primary and secondary prevention across the study period.

The indications for the insertion of the devices were spread out evenly between the primary and secondary prevention (n = 212 and n = 181 respectively). The most common indication for primary prevention was Ischaemic Cardiomyopathy (24.4%) and the most

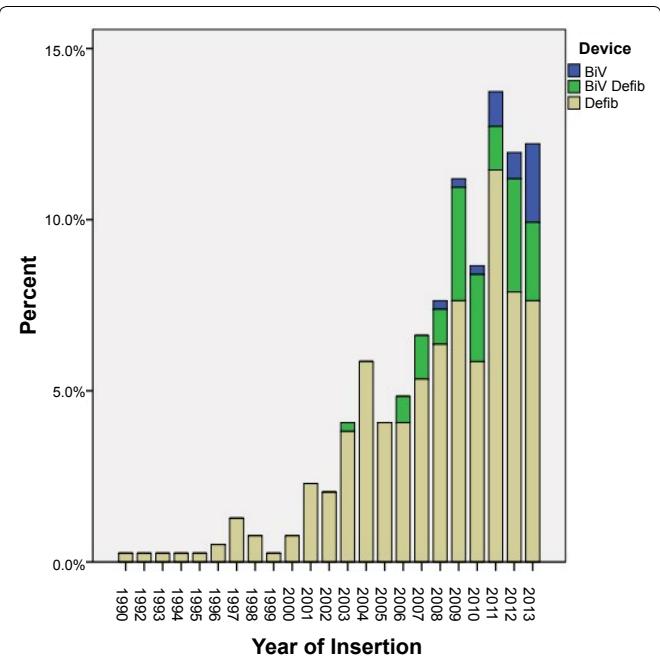


Figure 3: Distribution of the devices inserted across the study period.

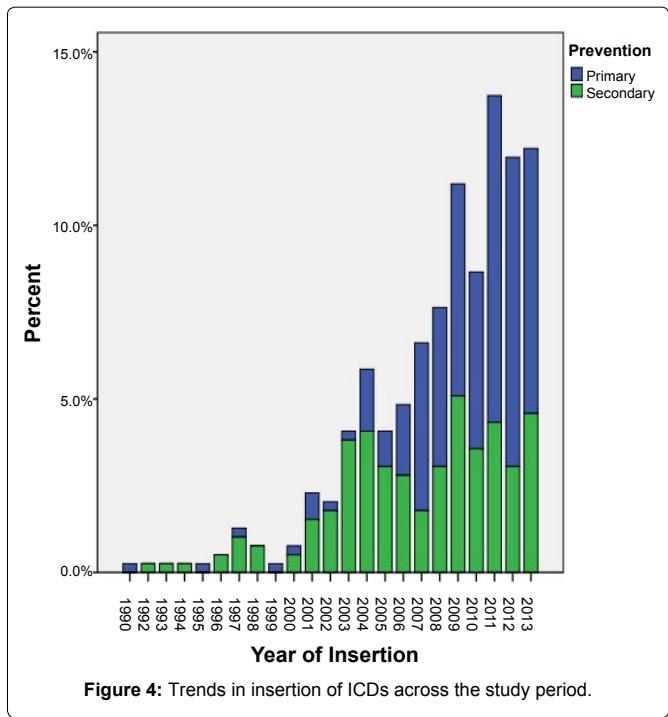


Figure 4: Trends in insertion of ICDs across the study period.

Table 2: Gender distribution for indications in insertion of ICDs.

Indication		Sex		P Value
		Male	Female	
Other	Dilated Cardiomyopathy	53	29	0.011
	HCM	11	4	(Chi square value 14.890)
	Ischaemic Cardiomyopathy	83	13	
	Other	17	2	
	Ventricular Fibrillation Arrest	44	17	
	Ventricular tachycardia	95	25	
Total		303	90	393

HCM = Hypertrophic Cardiomyopathy; Other: Wolff-Parkinson-White syndrome, Haemochromatosis, Complete Heart Block, Brugada, Idiopathic, Long QT syndrome & Denon's Cardiomyopathy.

common arrhythmia associated with secondary prevention was Ventricular Tachycardia (28.5%) of which 71% was ischaemic in origin and 29% was non-ischaemic in origin. The indication and gender cross tabulation is shown below in Table 2, overall indications

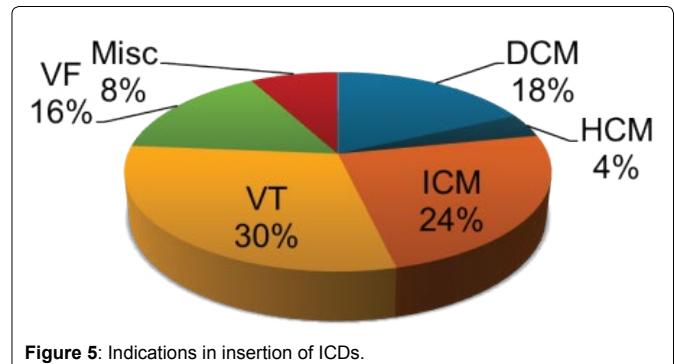


Figure 5: Indications in insertion of ICDs.

VF = Ventricular Fibrillation; Misc = Miscellaneous (other in the tables); DCM = Dilated Cardiomyopathy; HCM = Hypertrophic Cardiomyopathy; ICM = Ischaemic Cardiomyopathy; VT = Ventricular Tachycardia.

for insertion of devices is shown in Figure 5. It was noted that new devices were much more common in males in all indications. There was a statistically significant association between the indication for devices and the gender of the population with a significant Chi square value of 14.890 and a p value of 0.011.

Mortality

It was noted that mortality over the study period was low at 7.88% (n = 31), however 72 patients were lost to follow up as they were not followed up at this practice after their device implantation hence their vital status is unknown.

Discussion

The use of ICD therapy to prevent Sudden Cardiac Death increased across the study period. The proportion of devices inserted for primary prevention increased from 23% to 63% after the MSAC approved the use of ICD for primary as well as secondary prevention. This is consistent with expanding indications for ICD therapy [10], and international trends [16,17]. The Swedish registry in 2012 reported 59% of devices were inserted for primary prevention [16] and the Italian registry in 2004 reported that 24% were for primary prevention [17].

Our patient group had a mean age of 66 yrs, which is similar to the Swedish (mean age 63 yrs) [16], Danish (mean age 66 yrs) [18] and Italian (mean age 68 yrs) [17] populations receiving this therapy, while one group from New Zealand quoted a mean age of 53 yrs [19]. It was also noted that majority of individuals receiving the device were males (77%) which is similar to the Swedish study [16]. Reviewing the results of Table 2 with the statistically significant Chi square value we can assume that being male with a cardiomyopathy was associated with an increased device insertion rate. However this study had a small sample size as compared to the various other studies hence further research may be required to answer this question from an Australian perspective. Many studies over the past decade and one recent study has shown that majority of ICDs are inserted in men as compared to women [20-22].

The first implant rates for ICD in 2011 for our study was 120 per 100,000 inhabitants which is in keeping with the European trends and the Swedish study which had 136 per million inhabitants [16,23].

The possible reasons why the trends were similar to the other countries and there was a significant increase in devices for primary prevention is possibly due to increased funding by the government for implantation and also for remote monitoring of ICD devices [11,24,25]. With the increased funding there was an increase in the access to healthcare especially for people living in the rural areas [25]. This helped in making Geelong a referral centre for rural Western Victoria.

There is evidence that patients over the age of 75 receive the same benefit as younger patients from ICD therapy in terms of preventing sudden cardiac death, however the older population have higher all

cause mortality rates [26]. For this reason, it is possible that the older population with multiple co-morbidities are less likely to receive ICD therapy.

The overall mortality rate in our study group was low at 7.88% as compared to the other series, which ranged from 19% and 36% [26,27]. However, given that The University Hospital Geelong serves as a referral centre for a major part of rural western Victoria a number of patients were lost to follow up hence their vital status is not known.

This study is a retrospective observational audit, hence suffers from a number of inherent limitations. Gaps exist in the data, as The University Hospital Geelong acts as a referral centre for a major part of rural western Victoria, number of patients were lost to follow up after their device implantation. As well, data may not have been always recorded according to the tightly defined criteria of this study. The results of this study do not represent the trends in the practice in Australia. This study was limited to procedures done in a large public hospital and did not capture the number of ICDs that were implanted within the private sector; hence it is difficult to say whether the trends described in the public sector were same in the private.

It was observed that there was an increasing rate of ICD implantation across the study period, with an increase in proportion of patients receiving this therapy for primary prevention. The previous large multicentre trials in heart failure patients receiving device therapy have shown higher mortality rates [28,29], so there is a possibility that this therapy is still not available to a wide enough patient group locally. This is supported by the young average age of implant recipients and the low overall mortality rate we found in this study. Further work on making this potentially lifesaving therapy more widely available in the Australian context is required.

Conclusion

After ICDs were approved for primary prevention in 2006 there was a dramatic increase in the number of devices inserted for this indication. Ischaemic Cardiomyopathy was the most common indication for primary prevention and Ventricular Tachycardia associated with ischaemic LV dysfunction being the most common arrhythmia in the secondary prevention group.

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Ethical Statement

This study was reviewed by the Barwon Health Research Office and was advised that this project is exempt from ethical review as outlined in the National Statement on Ethical conduct in Human Research Section 5.

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